

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No. 7,097,834
Issue date August 29, 2006
Inventors William J. Boyle
For OSTEOPROTEGERIN BINDING PROTEINS

Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

RESPONSE TO REQUIREMENT FOR INFORMATION
IN APPLICATION FOR EXTENSION OF PATENT TERM UNDER 35 U.S.C. § 156

Further to the Requirement for Information dated October 19, 2010, the period for response having been extended to March 19, 2011, by a petition for a three (3) month extension of time under 37 C.F.R. § 1.136 and fee payment concurrently filed herewith, and further to the Application for Extension of Patent Term Under 35 U.S.C. § 156 dated July 27, 2010 ("the Application"), Applicant submits the following information.

The Requirement for Information states that "[i]t is unclear how a product merely described as 'a fully humanized monoclonal antibody which binds to human RANKL' in the PTE Application at 1 and on the package insert as 'a RANK ligand (RANKL) inhibitor' meets the claim limitation of 'an antagonist antibody or binding fragment thereof which binds to the osteoprotegerin binding protein of SEQ ID NO: 39.'"

Applicant directs the Office's attention to page 11, section 12.1 of the PROLIA® package insert, which states:

Prolia prevents RANKL from activating its receptor, RANK, on the surface of osteoclasts and its precursors. Prevention of the RANKL/RANK interaction inhibits osteoclast formation, function and survival, thereby decreasing bone resorption and increasing bone mass and strength in both cortical and trabecular bone.

This demonstrates that the product meets the limitation of “an antagonist antibody,” as the product binds to RANKL and prevents the activation of RANK, thereby inhibiting bone resorption (as recited in Claim 1) and inhibiting osteoclastogenesis (as recited in Claim 15).

Applicant also directs the Office’s attention to page 11, section 11 of the PROLIA® package insert, which states that “Prolia (denosumab) is a human IgG2 monoclonal antibody with affinity and specificity for human RANKL....”

The amino acid sequence of human RANKL as shown in SEQ ID NO: 13 of U.S. Patent No. 6,740,522 (which is also the subject of a PTE Application for PROLIA®) is identical to the amino acid sequence of osteoprotegerin binding protein as shown in SEQ ID NO: 39 of the patent which is the subject of the present PTE Application, U.S. Patent No. 7,097,834.

Taken together, these demonstrate that the product meets the limitation of “an antibody or binding fragment thereof which binds to the osteoprotegerin binding protein of SEQ ID NO: 39”.

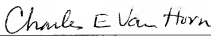
Applicant acknowledges a duty to disclose to the Director of the Patent and Trademark Office and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought in this application.

The prescribed fee for receiving and acting upon the application for extension of \$1,120.00 was enclosed with the Application. Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge Deposit Account No. 06-0916 for any such fees. Should a refund of fee paid be necessary, the Commissioner is hereby authorized to credit any such amount to Deposit Account No. 06-0916.

The undersigned is a registered practitioner of the United States Patent and Trademark Office and is authorized by the Applicant to act on behalf of the Applicant.

Respectfully submitted,

Date: March 18, 2011



Charles E. Van Horn
Reg. No. 40,266